How to Write CDC IRB Reports and How to Review Responses to CDC IRB Reports
A Guide to CDC IRB Members

The purpose of this document is to provide guidance to CDC IRB members in writing IRB reports and reviewing responses to IRB reports.

Writing the Report

If after the IRB reviews a protocol action (either as a convened board or through the expedited review process) it is determined that there are issues that need to be addressed prior to the IRB's approving the protocol, the primary reviewer will write a report that describes the actions that the IRB has taken and any action that the Board is requesting of the investigator prior to approval. The report is written in consultation with the IRB Chair or Co-chair, other IRB members, as needed, or the Human Subjects Activity in some instances. The Human Subjects Activity will provide the WordPerfect report format document to IRB members. Also, examples of IRB reports are available to IRB members upon request.

The report format is designed to communicate to the CDC investigator the IRB's issues and concerns. The first section of the report, "General Comments and IRB Actions," should tell the investigator exactly what action has been taken by the IRB. It should state whether the protocol action was reviewed by the convened board or through the expedited review process. The determination of the level of risk for the study should be included here. If the action was expedited, the report should state under which research category(ies) it was expedited. (See 45 CFR 46.110(b)(1) and the list of expeditable research categories.) Primary reviewers are asked to confirm the research category(ies) under which the action was expedited and to include in this section of the report any additional categories that may be applicable to the protocol. This section of the report should also tell the investigator if the action was approved pending receipt of satisfactory responses to the issues and concerns that will be outlined in the report; or if action was deferred, with a brief summary explaining why action was deferred and what additional information is required before the Board can reconsider the protocol. If the requested action was disapproved, the IRB must explain why and describe substantive modifications to the protocol that should be made before it may be resubmitted for IRB review. (Note: Disapproval requires the action of the majority of the convened board; a single reviewer may not disapprove an action through the expedited review process.)

The "General Comments and IRB Actions" section should also state whether the Board has approved (or may consider approving) any of the "big three" waivers, i.e., waiver of informed consent or assent (in accordance with 45 CFR 46.116(d) or 46.408(a)), waiver of documentation of informed consent (in accordance with 45 CFR 46.117(c)(1) or (2)), or waiver of parental permission (in accordance with 45 CFR 45.116(d) or 46.408(c)). If investigators need to further address issues regarding any of these waivers, they should be detailed under "Protocol Issues."

The remainder of the report is divided into three categories that address (1) protocol issues, (2) consent form issues, and (3) addenda issues (e.g., scripts, questionnaires, brochures, etc.)

These categories are further subdivided as follows:

Response Required, Action Required. These are issues for which the IRB requires (in compliance with 45 CFR 46) that investigators provide a written response and that they make the necessary revisions to the protocol, consent form, or other related documents before the protocol can be approved. Please consider including a brief explanation as to how the requested changes relate to the protection of human subjects, provide guidance, and/or provide examples of suggested revisions.

Reviewers should strive to clearly describe the issue or concern and the corrective action being requested of the investigator. For example, if the Board believes that the protocol as submitted does not adequately describe how investigators will maintain the confidentiality of the data or the privacy of the participants, the report should clearly outline why this is a problem and exactly what action is required (e.g., "Please include in the revised protocol a section that describes the procedures that will be in place to ensure confidentiality of the data and the privacy of the individual, such as password protected databases, locked file cabinets, etc...").

Response Required, Action Optional. These are issues for which the IRB requires that investigators provide a written response, but for which approval is not contingent upon investigators' acceptance of the suggested changes. This section is where reviewers should include any "recommendations" or "suggestions" (rather than "requirements") that the Board believes will enhance the IRB's understanding of the study's purpose and/or design or may clarify issues for participants. Although the IRB is not requiring any action of the investigator (i.e., specific revisions to the protocol, consent forms, or other related documents), the investigator's response should indicate to the IRB that he/she has considered the scientific and ethical impact and consequences of these issues.

Of Note (for information only; no response or action required). This section should include minor comments such as notes of grammatical or typographical errors, errors in skip patterns in questionnaires, etc. Although the IRB is not requiring any response or action on the part of the investigators, these are generally issues the Board believes that if corrected would improve the overall written presentation of the protocol, but may not directly affect the human subjects involved in the research.

Any waivers of any of the required elements of informed consent (see 45 CFR 46.116(a)) or alterations of the informed consent process (other than the "big three" waivers) that the Board may grant at its discretion and without having received a specific request and justification from the investigator should be included as "of notes" in the IRB report. If the protocol was reviewed by the convened board, the justification for granting these waivers and/or alterations will be documented in the minutes of the meeting. If the protocol was reviewed through the expedited review process, the justification should be included in the report to the investigators (as there would be no meeting minutes in which to document the Board's

action). For use in these instances, the Human Subjects Activity has developed standard language for several of the more commonly waived/altered elements of informed consent and will provide the WordPerfect document to IRB members for their use in preparing IRB reports

After the reviewer has completed the report, he/she should forward it to the Chair or Co-Chair for concurrence. Upon concurrence by the Chair or Co-Chair, they should transmit the Board's report to the "Human Subjects Review-OD" (HSR-OD) electronic mailbox. Reviewers may transmit the Board's report to the HSR-OD mailbox on behalf of the Chair or Co-Chair as long as he/she states in the e-mail transmission that the report is being transmitted with their concurrence. Reviewers are asked **not** to cc the HSR-OD mailbox on transmissions of the draft report back and forth between members. The Human Subjects Activity will transmit the final official report to the CDC investigator.

Thoughts on Style and Tone

1. Remember that the persons with who you are communicating are your colleagues, deserving of basic respect as professionals. Assume that they are acting in good faith until they persuade you to suspect otherwise.

2. Be direct, specific, and polite in requesting additional information or modifications. If your request refers to less obvious requirements in 45 CFR 46, please provide a brief explanation about how the issue relates to the protection of human subjects to educate the investigator for future reference.

3. List items in the report in order of their importance and seriousness so that investigators can clearly understand which issues and concerns are your highest priorities.

4. Use active voice. For example:

   "Please describe the specific study procedures in the consent form...." (active)

   rather than

   "The consent form should include more details on the procedures...." (passive)

5. Eschew superfluous obfuscation (speak plainly).

6. Use points identified on the checklists to set up the outline of your report. The general protocol and informed consent/assent checklists are especially helpful in this regard.

7. Resist the urge to micromanage. Before requiring a change, please consider whether it is essential to the investigator's ability to conduct a scientifically sound and ethical study.

8. Don't speculate–ask for clarification or more detail if you are unsure about the investigators' intentions.

9. Remember that the IRB is not the Typo Gestapo–if the document contains a significant number of typos and/or grammatical errors, a general comment under *Of Note* should suffice.

Reviewing the Response to the Report

When the response to the report is received by the Human Subjects Activity from the investigator, it will be forwarded to the chair and primary reviewer. In consultation with the Chair or Co-Chair, the primary reviewer should determine whether the response adequately addresses the issues and concerns outlined in the report. If so, the reviewer should transmit his/her recommendation for approval to the Chair or Co-Chair. If the Chair or Co-Chair concurs with the recommendation, he/she will forward the final approval to the Human Subjects Review - OD mailbox. The primary reviewer may transmit the Board's final approval to the HSR-OD mailbox on behalf of the Chair or Co-Chair as long as he/she states in the e-mail transmission that the approval is being transmitted with their concurrence. The Human Subjects Activity will transmit the official approval memo to the CDC investigator.

If the primary reviewer and Chair or Co-Chair determine that there are still outstanding unresolved issues, the primary reviewer will prepare report #2, following the same procedures outlined above for report #1. If the primary reviewer and Chair or Co-Chair are still not satisfied with the response to a second report, please inform the IRB Administrator and the Human Subjects Manager immediately. At this point, it may be necessary to request assistance from the CDC Deputy Associate Director for Science or the CIO's Associate Director for Science to try and resolve the remaining issues.

IRB members may contact their IRB Administrator or the Human Subjects Manager at (404) 639-4500 at any time with any questions they may have regarding the preparation of an IRB report or the review of a response to a report.